SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING FEBRUARY 23, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on February 23, 1999, at 11 a.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency's (EPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. A list of parking lot issues is given in Attachment C. Attachment D presents the guiding principles, comment acknowledgment form letter, and commenter template. *The purpose of the meeting was to review action items from previous meetings and discuss comments received at the NELAC IVi* meetings.

REVIEW ACTION ITEMS, ISSUES FROM NELAC IVI AND PARKING LOT

The committee reviewed the action items from NELAC IVi, the January 5th and 28th meetings, and homework assignments from NELAC IVi. Action items that have not been addressed are listed in Attachment A.

The committee decided that including the lists of records and procedures, which QS Committee participants previously developed, would be a useful guide for users of the Chapter 5. It was decided that these guides will be included in an appendix with a separate section for each list and an explanatory paragraph. The appendix would not require a vote of approval.

The committee decided to change the language in Section 5.1.b to address the issue of not being able to determine whether the requirements of an analytical method specified by a regulatory program are more or less stringent than the NELAC requirements. In those situations, the laboratory should follow the requirements of the regulatory program's method. The QS Committee participants felt that this provided more flexibility for the regulatory programs and would avoid a situation where the laboratory would have to perform an analysis under both sets of requirements. Section 5.9.4.2 will be revised to be consistent with Section 5.1.b.

Comments were received from Mr. Richard Reding of EPA. The committee decided that they should wait for consensus comments from the Environmental Monitoring Management Council (EMMC) rather than address individual comments from within EPA. However, individual comments may be addressed along with EMMC comments. Comments were also received from the State of New Hampshire, Department of Environment.

DISCUSSION OF ISSUES RAISED AT NELAC IVI

The committee agreed that it is premature to address field measurement quality control (QC) issues and that it should stay focused on the laboratory quality system at this time.

The committee also discussed the issue of a laboratory having sufficient data to warrant conducting an onsite assessment. A point was raised that it may not be an effective use of an auditor's time to visit a laboratory that is accredited for a specific analytical method(s), but

doesn't actually perform any analyses for clients. A counterpoint was made that commercial laboratories may need to be certified for certain methods to satisfy contractual requirements or for marketing purposes. Mr. Slayton will address this issue as an item on the list of frequently asked questions.

The QS Committee discussed the concept of the "work cell," a common practice in laboratories where more than one analyst is involved the analysis process, and how this affects training and demonstrating capability. The committee agreed that the key issue is that the product of the group's work must meet the QC requirements. In addition, the chapter of the standards must be flexible enough to allow analysts to move between different work cells.

Section 5.9.4.1.f will be divided broken into two sections (f and g), one covering the use of autoclaves for sterilization and one for use with the chemical analyses.

Editorial changes were made to Section 5.9.4.2.1.a to clarify its meaning.

The next QS Committee teleconference is scheduled for March 3, 1999 from 11 a.m. to 2 p.m. EST. The call-in number is (202) 260-8330 and the access code is 8983#.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
FEBRUARY 23, 1999

Item No.	Action Item	Date to be Completed
1.	Mr. Cross to prepare draft minutes of the teleconference.	February 24, 1999
2.	Mr. Slayton to compile a list of changes made to Chapter 5.	
3.	Mr. Siders to draft a FAQ about why the QS Committee decided to revisit calibration and detection.	
4.	Mr. Slayton to draft a FAQ about ensuring laboratories have sufficient data for an onsite assessment when MDL standards change.	
5.	Mr. Mendenhall to distribute to the QS Committee his draft regarding Section 5.10.2.1.d, method validation.	
6.	QS Committee will revisit the issue of whether matrix spikes and matrix spike duplicates are practical and essential.	
7.	Mr. Slayton to add a new guiding principle/review criteria item of strengthening the link between data quality and use of the data.	
8.	Mr. Frederici and Mr. Porterfield to draft introductory paragraphs for the new appendix containing a list of records and procedures required by Chapter 5.	
9.	Mr. Slayton to acknowledge receipt of Mr. Reding's comments and explain the QS Committee approach to addressing comments from EPA.	
10.	QS Committee to review Section 5.9.4.2.1 for the next teleconference.	Prior to next teleconference

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
FEBRUARY 23, 1999

Name	Affiliation	Phone/Fax/E-mail
Slayton, Joseph Chair	U.S. EPA/Region 3	T: 410-305-2653 F: 410-305-2698 E: slayton.joe@epamail.epa.gov
Bruch, Mary	Mary Bruch Micro Reg. Inc.	T: 703-589-1514 F: 703-779-0267 E: --- none ---
Frederici, Raymond	Recra Labnet	T: 708-534-5200 F: 708-534-5211 E: frederir@recra.com
Glowacki, Clifford (Absent)	Ashland Chemical Co.	T: 614-790-3482 F: 614-790-4294 E: cglowacki@ashland.com
Labie, Sylvia	Florida Dept. of Environmental Protection	T: 904-488-2796 F: 904-922-4614 E: labie_s@dep.state.fl.us
Mendenhall, David	Utah Dept of Health	T: 801-584-8470 F: 801-584-8501 E: dmendenh@doh.state.ut.us
Meyers, Sheila	TNRCC	T: 512-239-0425 F: 512-239-6307 E: smeyers@.tnrcc.state.tx.us
Nielsen, Jeffrey	City of Tallahassee, Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
Porterfield, Donivan (Absent)	Los Alamos National Lab., AQ & CIM	T: 505-667-4710 F: 505-665-4737 E: dporterfield@lanl.gov
Siders, Scott	Illinois EPA	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
Siegelman, Fred	USEPA/ORD/QAD	T: 202-564-5173 F: 202-565-2441 E: siegelman.frederic@epamail.epa.gov
Cross, Mike (Contractor Support)	Research Triangle Institute	T: 202-728-2045 F: 202-728-2095 E: myc@rti.org

Attachment C

PARKING LOT ITEMS/ISSUES AND
FREQUENTLY ASKED QUESTIONS
QUALITY SYSTEMS COMMITTEE
FEBRUARY 23, 1999

Items/issues will remain in the Parking Lot until they are completed.

1. Question: If a mandated method (required by EPA or State Authority) is less stringent than the QS standards what do I follow?

Answer: The most restrictive/demanding.

2. Question: Do the QS standards require the use of any specific method?

Answer: No

3. Question: Do the QS standards allow for the use of the performance-based measurement systems (PBMS) approach?

Answer: Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

4. Question: Do the QS standards apply to small laboratories?

Answer: Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented SOPs and QC procedures) more then upon the size of the laboratory.

5. Question: If my laboratory is measuring high level concentrations and is set-up (perhaps even optimized) to analyze at such levels and is only interested in whether a high level regulatory limit is exceeded, why do I have to determine a detection limit?

Answer: A detection limit is considered essential to verify (confirm and document) that the laboratory is actually able to detect and measure at the regulatory or decision limit. Detection limit determinations are also considered an important consideration with regard to the quantitation range selection particularly with regard to the choice of the concentration of the lowest calibration standard. Changes to the standard will be proposed at the January 1999 Interim Meeting, which no longer specify that the MDL (40 CFR Part 136) procedure be employed, unless it is mandated by the test method or applicable regulation. In the proposed revision, the term "detection limit" may not be the lowest concentration level attainable by a given analytical method, but rather that it is a concentration that is actually measurable (and verified) using the procedures, e.g.,

equipment, analytical method, routinely employed for sample analyses (could be relatively high concentration). The detection level should be appropriate or relevant for the intended use of the data. In some cases this will of necessity be the lowest concentration level attainable, e.g., low level drinking water or wastewater permit limits.

Attachment D

ACKNOWLEDGEMENT LETTER, REVIEW GUIDELINES, AND COMMENTER TEMPLATE
QUALITY SYSTEMS COMMITTEE
FEBRUARY 23, 1999

Date:

Dear :

On behalf of the Quality Systems Committee, thank you for your comments on the Chapter 5 standards of the National Environmental Laboratory Accreditation Conference (NELAC). The standards are routinely reviewed and updated. Continual improvement of the standards is the focal point of NELAC process. We encourage your continued written input as well as your attendance at the NELAC interim meeting and yearly conference. Also, our committee routinely schedules 1-2 open forum meetings during each calender year.

Our committee requests that all comments be supplied in electronic format (WordPerfect if possible) and that handwritten, hardcopy and the use of color fonts be avoided. Comments are considered by the QS committee on a first come basis. We have placed a template (table) for comments on the NELAC Web page, which we hope will ensure that the processes is efficient. With this process we hope that emphasis can be placed on consideration of the comments so that the available time is not spent in the mechanics of exchanging information (US Mail and re-typing comments). Routinely, each set of comments is assigned a QS leader who will complete the comment table including suggested language for any proposed changes to the NELAC standards. The Leader will guide a discussion of the comments during routine committee meetings. The minutes of the meeting (posted on the web site) will capture the information in the completed table from committee discussions, thoughts/rationale and present the final decisions.

Again, thank you for taking the time and effort to improve the NELAC Quality System standards.

Sincerely,

Joseph Slayton, Chair
Quality Systems Committee

QS Approach: Comments Received and QS Response:

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following table:

Comment ID #: , Source of Comments (Name): QS Lead on Response (Name):			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled In by Commentor)	**COMMENTwith Rationale to QS (To Be Filled in my Commentor)** **New Wording for Standard (To Be Filled In by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**